BEFORE THE MEDICAL BOARD OF CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:)
RUDOLPH JOSEPH SCHROT, M.D.) Case No. 02-2012-225246
Physician's and Surgeon's)
Certificate No. A 70871)
)
Respondent)
)

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on February 26, 2016.

IT IS SO ORDERED: January 28, 2016.

MEDICAL BOARD OF CALIFORNIA

Howard Krauss, M.D., Chair

Panel B

1	KAMALA D. HARRIS		
2	Attorney General of California JOSE R. GUERRERO		
3	Supervising Deputy Attorney General MARA FAUST		
4	Deputy Attorney General State Bar No. 111729		
5	1300 I Street, Suite 125 P.O. Box 944255		
6	Sacramento, CA 94244-2550 Telephone: (916) 324-5358		
7	Facsimile: (916) 327-2247 Attorneys for Complainant		
8	BEFORE THE		
9			
10	STATE OF CA	ALIFORNIA	
11	In the Matter of the Accusation Against:	Case No. 02-2012-225246	
12	RUDOLPH J. SCHROT, M.D. 2800 L. Street, Suite 500	OAH No. 2014100817	
13	Sacramento, CA 95816-5616	STIPULATED SETTLEMENT AND	
14	Physician's and Surgeon's certificate No. A70871	DISCIPLINARY ORDER	
15	Respondent.		
16			
17	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
18	entitled proceedings that the following matters are true:		
19	<u>PARTIES</u>		
20	Kimberly Kirchmeyer ("Complainant") is the Executive Director of the Medical	
21	Board of California. She brought this action solely in her official capacity and is represented in		
22	this matter by Kamala D. Harris, Attorney General of the State of California, by Mara Faust,		
23	Deputy Attorney General.		
24	2. Respondent Rudolph J. Schrot, M.D. ("Respondent") is represented in this proceeding	
25	by attorney Stephen M. Boreman, Slote, Links & Boreman, LLP, whose address is: 1		
26	Embarcadero Center, Suite 400, San Francisco, CA 94111		
27	3. On or about February 11, 2000, the Mo	edical Board of California issued Physician's	
28	and Surgeon's certificate No. A70871 to Rudolph I. Schrot, M.D. (Respondent). The Physician's		

and Surgeon's certificate was in full force and effect at all times relevant to the charges brought in Accusation No. 02-2012-225246 and will expire on July 31, 2015, unless renewed.

JURISDICTION

- 4. Accusation No. 02-2012-225246 was filed before the Medical Board of California (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on September 23, 2014. Respondent timely filed his Notice of Defense contesting the Accusation.
- 5. A copy of Accusation No. 02-2012-225246 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 02-2012-225246. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 02-2012-225246, if proven at a hearing, constitute cause for imposing discipline upon his Physician's and Surgeon's Certificate.

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- 10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.
- 11. Respondent agrees that his Physician's and Surgeon's Certificate is subject to discipline and he agrees to be bound by the Board's imposition of discipline as set forth in the Disciplinary Order below.

CIRCUMSTANCES IN MITIGATION

12. Respondent Rudolph J. Schrot, M.D. has never been the subject of any disciplinary action. Respondent was not the treating physician and he did not participate in surgery. Furthermore, Respondent acted at the request of the surgeon and treating physician, who was the Chairman of Neurosurgery for his university medical center. Respondent's role was limited to obtaining a live Enterobacter aerogenes for surgical use by the surgeon and Chairman of the Department.

<u>RESERVATION</u>

13. The admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Medical Board of California or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

14. This stipulation shall be subject to approval by the Medical Board of California. Respondent understands and agrees that counsel for Complainant and the staff of the Medical Board of California may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal

action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 15. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Physician's and Surgeon's certificate No. A70871 issued to Respondent Rudolph J. Schrot, M.D. (Respondent) is publically reprimanded pursuant to Business and Professions Code section 2227. This public reprimand is issued in connection with Accusation No. 02-2012-225246, as follows:

On or about March 3, 2011, Patient #3 was taken to surgery at a university medical center. You were not the treating physician or surgeon. The Chairman of Neurosurgery was the surgeon and treating physician for Patient #3. The Chairman requested that you provide him with live Enterbacter aerogenes for implantation during neurosurgery, which the Chairman contended would be innovative treatment. You had previously requested the opinion of the IRB Director, who recommended IRB approval prior to treatment with the live culture. You relayed this information to the Chairman, who decided to proceed without IRB approval. You accepted your Chairman's decision to proceed without IRB approval and obtain the live culture for the Chairman to use during surgery. This public reprimand pursuant to Code section 2227 is issued to you with the expectation that such conduct will not be repeated.

IT IS FURTHER ORDERED that Respondent comply with the following:

1. PROFESSIONALISM PROGRAM (ETHICS COURSE). Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a professionalism program, that meets the requirements of Title 16, California Code of Regulations (CCR) section 1358. Respondent shall participate in and successfully complete that program. Respondent shall provide any information and documents that the program may deem pertinent. Respondent shall successfully complete the classroom component of the program not later than six (6) months after Respondent's initial enrollment, and the longitudinal component of the program not later than the

time specified by the program, but no later than one (1) year after attending the classroom component. The professionalism program shall be at Respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

A professionalism program taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the program would have been approved by the Board or its designee had the program been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the program or not later than 15 calendar days after the effective date of the Decision, whichever is later.

2. VIOLATION OF THIS AGREEMENT. Failure to fully comply with any term or condition of this agreement is unprofessional conduct. If Respondent violates this agreement in any respect, the Board may reinstate the accusation and/or file an amended accusation.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Stephen M. Boreman. I understand the stipulation and the effect it will have on my Physician's and Surgeon's certificate. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Medical Board of California.

DATED:

10/16/2015

Respondent

I have read and fully discussed with Respondent Rudolph J. Schrot, M.D. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.

I approve its form and content.

DATED:

10/16/2015

Stephen M. Boreman Slote, Links & Boreman, LLP Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Medical Board of California.

Dated: 10/19/15

Respectfully submitted,

KAMALA D. HARRIS Attorney General of California Jose R. Guerrero Supervising Deputy Attorney General

Mara Faust

Deputy Attorney General Attorneys for Complainant

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Exhibit A

Accusation No. 02-2012-225246

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1	KAMALA D. HARRIS Attorney General of California		
2	E. A. JONES III Supervising Deputy Attorney General		
3	MARA FAUST Deputy Attorney General	FILED	
4 -	State Bar No. 111729	STATE OF CALIFORNIA COLORDO OF CALIFORNIA	
5	1300 I Street, Suite 125	PAMENTO SEPTEMBY 23/ 2014 ANALYST	
6	Sacramento, CA 94244-2550 Telephone: (916) 324-5358	MINES	
7	Facsimile: (916) 327-2247 Attorneys for Complainant		
8		IF.	
9	BEFORE THE MEDICAL BOARD OF CALIFORNIA DEPARTMENT OF CONSUMED AFFAIRS		
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
11	In the Metter of the Acquestion Assinct	Case No. 02-2012-225246	
12		A C C U S A T I O N	
13	2800 L. Street, Suite 500	ACCUSATION	
14	Sacramento, CA 95816-5616		
15	Physician's and Surgeon's Certificate No. A70871		
16	Respondent.		
17			
18	Complainant alleges:		
19	PARTIES		
20	Kimberly Kirchmeyer (Complainant) bring	gs this Accusation solely in her official	
21	capacity as the Executive Director of the Medical Boar	rd of California, Department of Consumer	
22	Affairs.		
23	2. On or about February 11, 2000, the Medical Board of California issued Physician's		
24	and Surgeon's Certificate Number A70871 to Rudolph Joseph Schrot, M.D. (Respondent). The		
25	Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the		
26	charges brought herein and will expire on July 31, 2015, unless renewed.		
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		Accusation	

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JURISDICTION

- 3. This Accusation is brought before the Medical Board of California (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
 - 4. Section 2227 of the Code states:
- "(a) A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code, or whose default has been entered, and who is found guilty, or who has entered into a stipulation for disciplinary action with the board, may, in accordance with the provisions of this chapter:
 - "(1) Have his or her license revoked upon order of the board.
- "(2) Have his or her right to practice suspended for a period not to exceed one year upon order of the board.
- "(3) Be placed on probation and be required to pay the costs of probation monitoring upon order of the board.
- "(4) Be publicly reprimanded by the board. The public reprimand may include a requirement that the licensee complete relevant educational courses approved by the board.
- "(5) Have any other action taken in relation to discipline as part of an order of probation, as the board or an administrative law judge may deem proper.
- "(b) Any matter heard pursuant to subdivision (a), except for warning letters, medical review or advisory conferences, professional competency examinations, continuing education activities, and cost reimbursement associated therewith that are agreed to with the board and successfully completed by the licensee, or other matters made confidential or privileged by existing law, is deemed public, and shall be made available to the public by the board pursuant to Section 803.1."
 - 5. Section 2234 of the Code states:

"The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

- "(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
 - "(b) Gross negligence.
- "(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.
- "(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.
- "(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.
 - "(d) Incompetence.

"

FIRST CAUSE FOR DISCIPLINE (Gross Negligence) (Bus. & Prof. Code, § 2234, subd. (b))

- 6. Respondent is subject to disciplinary action under Code section 2234, subdivision (b), in that Respondent was grossly negligent when he offered and facilitated innovative therapy to patients, outside of Institutional Review Board (IRB) approval, for the treatment of their glioblastoma brain tumors. The circumstances are as follows:
- 7. In or about October 2010 through March 2011, Respondent was involved in the treatment of three patients with glioblastoma (GBM) brain tumors, at U.C. Davis Hospital, with an intervention that involved the administration of live bacterial cultures of Enterobacter aerogenes¹ into the patient's brain, in the tumor operative bed. This procedure was done under the theory that the live bacteria would induce the immune system to attack the tumor and prolong

¹ The Enterobacter aerogenes employed in the three patient cases was live animal fecal bacteria.

survival. In general, because the average survival period for patients with GBMs is fifteen months, other experimental therapies are used in many patients such as the use of immunotherapy, viral therapy, anti-angiogenic therapy, radiosurgery and targeted agent chemotherapy.

- 8. On October 17, 2010, Patient #1² was taken to surgery. This was a 56-year-old male with recurrent glioblastoma in the brainstem. The patient's attending physician³ asked Respondent to provide the bacterial cultures that would be administered to the brain by the attending physician during the surgery. In addition, Respondent was involved in the patient's preoperative consultation and informed consent process regarding intentional wound infection as part of the treatment plan and the patient's post-operative care.
- 9. Prior to Patient #1's surgery, Respondent sought clarification with the IRB director at U.C. Davis, who communicated that the proposed therapy did not appear to require human studies review and that, in his opinion, the therapy likely did not require IRB or FDA oversight as a single use "innovative treatment" or nonstandard treatment. The IRB director at Davis cannot provide approval from the IRB. It is not clear that Respondent informed the IRB director at U.C. Davis that the bacterial cultures were not approved for human use.
- 10. Respondent believed that the placement of live bacteria in a patient's brain constituted "innovative therapy" (synonymous with unorthodox therapy) as opposed to "research." Respondent used the concept that the treatment constituted "innovative therapy" not requiring IRB approval which then left the neurosurgeons having to provide informed consent regarding all the risks and benefits. Respondent did not include in the informed consent form that this approach had never been tried in humans, and Respondent implied a causal link between "unexpected long survival" and "infections in the tumor bed &/or bone flap" in the informed consent form that he wrote for the patients. Such statements regarding a causal link between prior patients' outcomes and the placement of bacteria could be and probably were misleading to vulnerable patients and their family when dealing with this terminal illness, especially given that

² Full patient names will be turned over later during discovery.

³ The same attending physician performed the surgery on all three patients referenced in this Accusation.

post operative gram negative bacterial brain infections are known to be life threatening neurological emergencies, requiring immediate and expeditious antibiotic therapy to eliminate such infection.

- 11. Patient #1 underwent surgery on October 17, 2010, that included a partial removal of the brainstem GBM, followed by installation of gelform soaked into Enterobacter aerogenes cultures, and replacement of the bone flap after soaking the flap in cultures of Enterbacter aerogenes. Patient #1 later became septic and over time an abscess signature was obtained from the tumor bed by MRI in the brainstem and the patient passed away. The family of Patient #1 stayed in the attending physician's house during the entire duration of the patients final therapy which may have made the family feel an obligation to the attending physician and the treating team to undergo a risky procedure.
- 12. Respondent's action of offering and facilitating treatment of recurrent glioblastoma to Patient #1 with placement of live Enterobacter aerogenes bacteria in the patient's brain, which was not approved for human use, as part of innovative therapy outside the IRB approval process constitutes gross negligence in violation of Code section 2234, subdivision (b).

SECOND CAUSE FOR DISCIPLINE (Gross Negligence) (Bus. & Prof. Code, § 2234, subd. (b))

- 13. Complainant hereby incorporates paragraphs 7, 9 and 10 of the instant Accusation as though fully set forth herein.
- 14. Respondent is subject to disciplinary action under Code section 2234, subdivision (b), in that Respondent was grossly negligent when he offered and facilitated innovative therapy to patients, outside of IRB approval, for the treatment of their glioblastoma brain tumors. The circumstances are as follows:
- 15. On or about November 19, 2010, Patient #2 was taken to surgery. This was a 56-year-old female with recurrent glioblastoma in the brain. The patient's attending physician asked Respondent to provide the bacterial cultures that would be administered to the brain by the attending physician during the surgery. In addition, Respondent was involved in the patient's

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preoperative consultation and informed consent process regarding intentional wound infection as part of the treatment plan and the patient's post-operative care.

- 16. Prior to Patient #2's surgery, Respondent sought clarification with the IRB director at U.C. Davis, who communicated that as the number of patients increased, the activity had the appearance of "research" and that it was recommended that an IND application be submitted to the Food and Drug Administration (FDA). Patient #2 underwent surgery on November 19, 2010, that included "installation of probiotic therapy consisting of Enterobacter into the tumor bed and in the bone flap." On October 6, 2011, Respondent noted in Patient #2's record that there was tumor regression. However, Patient #2 required bone flap removal for what was deemed a chronic infection of the wound and died one month after the declared tumor regression.
- 17. Respondent's action of offering and facilitating treatment of recurrent glioblastoma to Patient #2 with placement of live Enterobacter aerogenes bacteria in the patient's brain, which was not approved for human use, as part of innovative therapy outside the IRB approval process constitutes gross negligence in violation of Code section 2234, subdivision (b).

THIRD CAUSE FOR DISCIPLINE (Gross Negligence) (Bus. & Prof. Code § 2234, subd. (b))

- 18. Complainant hereby incorporates paragraphs 7, 9, 10 and 16 of the instant Accusation as though fully set forth herein.
- 19. Respondent is subject to disciplinary action under Code section 2234, subdivision (b), in that Respondent was grossly negligent when he offered and facilitated innovative therapy to patients, outside of IRB approval, for the treatment of their glioblastoma brain tumors. The circumstances are as follows:
- 20. On or about March 3, 2011, Patient #3 was taken to surgery. This was a 61-year-old female with newly diagnosed glioblastoma in the brain. The patient's attending physician asked Respondent to provide the bacterial cultures that would be administered to the brain by the attending physician during the surgery. In addition, Respondent was involved in the patient's

preoperative consultation and informed consent process regarding intentional wound infection as part of the treatment plan and the patient's post-operative care.

- 21. Prior to Patient #3's surgery, Respondent sought clarification with the IRB director at U.C. Davis, who communicated that Respondent should seek IRB and FDA oversight. The attending physician's response to this advice, once Respondent discussed this issue, was to say, "I don't need it." Patient #3 underwent surgery on March 3, 2011, that included "installation of probiotic therapy consisting of Enterobacter [aerogenes] into the tumor bed and in the bone flap" and the bacteria was again supplied with the assistance of Respondent. Patient #3 developed sepsis, lapsed into a coma, developed a purulent ventriculitis and died within two weeks of therapy rather than surviving the average fifteen months.
- 22. Respondent's action of offering and facilitating treatment of recurrent glioblastoma to Patient #3 with placement of live Enterobacter aerogenes bacteria in the patient's brain, which was not approved for human use, as part of innovative therapy outside the IRB approval process constitutes gross negligence in violation of Code section 2234, subdivision (b).

FOURTH CAUSE FOR DISCIPLINE (Repeated Negligent Acts) (Bus. & Prof. Code, § 2234, subd. (c))

- 23. Respondent is subject to disciplinary action under Code section 2234, subdivision (c), in that he engaged in repeated negligent acts in the care and treatment of three patients with glioblastoma brain tumors. The circumstances are as follows.
- 24. The facts and circumstances alleged in paragraphs 7 through 11, 14 through 16 and 19 through 21 of the instant Accusation as though fully set forth herein.
- 25. Respondent's action of offering facilitating treatment of recurrent glioblastoma to Patient #1 with placement of live Enterobacter aerogenes bacteria in the patient's brain, which was not approved for human use, as part of innovative therapy outside the IRB approval process constitutes negligence in violation of Code section 2234, subdivision (c).
- 26. Respondent's action of offering and facilitating treatment of recurrent glioblastoma to Patient #2 with placement of live Enterobacter aerogenes bacteria in the patient's brain, which